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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6006

October 23, 2003 "Archive"

CERTIFIED MAIL –
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Cornell Adams
President
Accurate Set Inc.
1199 Broad Street
Newark, NJ 07114

04-NWJ-05

Dear Mr. Adams:

During an inspection of your firm, Accurate Set Inc., located at 1199 Broad Street, Newark, NJ between September 10, 2003-September 16, 2003, an investigator from the Food and Drug Administration (FDA) determined that you manufacture Fast Set Alginate, Alginate White Non-Flavored, Poly V Putty, and Polysil Putty. These products are medical devices within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Quality System Regulation (QSR) for medical devices as set forth in Title 21, Code of Federal Regulations (CFR) Part 820. The deviations from QSR include, but are not limited to, the following:

1. Device master records have not been established to include production process specifications, quality assurance procedures and specifications including acceptance criteria, and packaging and labeling specifications as required by 21 CFR 820.181. There were no written specifications for processing including the equipment used, the order of mixing of components, and mixing times.

2. The device history records failed to demonstrate that the devices were manufactured in accordance with the device master records as required by 21 CFR 820.184. Specifically, the following device history records do not include

the information pertaining to processing, packaging, labeling, and release testing from the beginning of the devices' manufacture through distribution:

A) Alginate white non-flavored, dated July 24, 2003.
B) Fast set Alginate (Batches # 1, 2, 3) dated July 31, 2003.
C) Poly v putty (Batch # 2) dated April 29, 2003.
D) Polysil putty (Batch # 1) dated July 2, 2003.

3. Complaint handling procedures have not been established as required by 21 CFR 820.198(a). Specifically, there is no written complaint handling procedure for receiving, reviewing, and evaluating complaints by a formally designated unit.

4. Procedures for conducting quality audits have not been established as required by 21 CFR 820.22. Specifically, your firm failed to conduct quality audits in order to verify that the quality system is effective in fulfilling your quality system objectives. There is no assurance that the processes used to manufacture your devices is operating in a state of control.

Furthermore, written medical device reporting (MDR) procedures have not been developed as required by 21 CFR 803.17. You are required as a manufacture of devices to have a written procedure that evaluates the events that may require reporting to the FDA of any death or serious injury caused or contributed by your devices.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and on the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems within your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective and preventive actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice to you. These actions include, but are not limited to, seizure, injunction and/or civil monetary penalties.

Please notify this office in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be directed to the New Jersey District, FDA, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Robert J. Maffei, Compliance Officer.

Sincerely,

Diana Amador-Toro for

Douglas I. Ellsworth
District Director
New Jersey District